

REMARKS

Applicants respectfully request reconsideration of the rejections set forth in the Office Action mailed June 15, 2004.

Claims 40-43 and 51 are pending and rejected. Applicants have amended claim 40 herein. The amendment to claim 40 finds support, for example, at page 24 of the specification and does not add new matter.

Applicants have amended claim 40 to better define one embodiment of the invention, notwithstanding the Applicants' belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals. None of the amendments to the claims is related to the statutory requirements of patentability unless expressly stated so herein.

The comments in the Office action are now addressed in turn.

Rejections Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Office rejected claims 40-43 and 51 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (Office Action at pages 2-3.) According to the Office claim 40, and claims 41-43 and 51 as they depend from claim 40, were amended to contain new matter in Applicants' previous reply. The Office's position is based on its views that "there does not appear to be support for the broadly encompassing language of 'producing a fingerprint. . .[,]' wherein the specification provides for only one methodology of 'producing a fingerprint' but not any others," and that "there [does not] appear to be support for the broadly encompassing

language of 'known behaviors in a database'." Applicants respectfully disagree with the Office's position and traverse this rejection.

Amended claim 40 recites a computer program product comprising "code for capturing a scalar morphological value derived from a first component of a cell and a second component of said cell from each of said plurality of manipulated cells for each of said plurality of different cell lines." This aspect of the computer program product is described, for example, at page 24, lines 7-9 and 11-17 of the application.

The computer program product of amended claim 40 also comprises "code for producing a fingerprint characterizing the manipulated cells, wherein the fingerprint comprises a vector of two or more of said scalar morphological values for the plurality of manipulated cells for each of the plurality of different cell lines." This aspect of the computer program product is described, for example, at page 24, lines 17-19.

The computer program product of amended claim 40 also comprises "code for producing a statistical profile of said manipulated cells by statistically comparing said fingerprint against fingerprints associated with application of said manipulation to cell lines in a database." This aspect of the computer program product is described, for example, at pages 14 and 15; at page 24, lines 21-27; and at page 25, lines 1-31.

As described in the application, a fingerprint may comprise scalar values, which are statistically analyzed by any suitable technique, such as clustering, heuristic classification, creation of a "phylogenetic tree," or a neural network-based approach. (See, for example, page 14, line 27 to page 15, line 31.) One exemplary embodiment disclosed in the application comprises conversion of a fingerprint comprising scalar values into a nucleotide or amino acid letter-based code, which is then analyzed and

compared to a database of similarly coded fingerprints using software and algorithms known in the art for genetic and peptide sequence comparisons. (See, for example, page 14, line 32 to page 15, line 5.) Another exemplary embodiment disclosed in the application uses fingerprints comprising numeric values directly, statistically analyzing the fingerprints using an approach comprising creation of a phylogenetic tree to assess statistical similarity between fingerprints in the database and a fingerprint obtained from a test manipulation. (See, for example, page 25, lines 6-9.)

Applicants submit that the application as filed demonstrates possession of the invention of claims 40-43 and 51. Accordingly, Applicants respectfully request that the rejection for lack of adequate written description be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)

The Office rejected claims 40-43 and 51 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (Office Action at pages 3-6.) In making this rejection the Office contends that the only specific example of code for producing a fingerprint described in the application is that provided at page 45, lines 19-24. Because the Office considers that determining other codes for producing a fingerprint would require "independent decision, judgments, tests, and validation," which in the Office's view are "not considered to be routine experimentation," the Office concluded that one of skill in the art "would be required to use inventive skill" to practice the invention. Applicants respectfully disagree with the Office's position and traverse this rejection.

In Applicants' presently claimed computer program product each fingerprint comprises "a vector of two or more of said scalar morphological values for the plurality

of manipulated cells for each of the plurality of different cell lines.” The scalar morphological values are “derived from a first component of a cell and a second component of said cell from each of said plurality of manipulated cells for each of said plurality of different cell lines.”

As described in Applicants’ specification, two or more scalar values extracted from a plurality of cell lines and markers grown in the same condition may be extracted to produce a fingerprint. Such a fingerprint comprises a “vector of two more scalar values extracted from a plurality of cell lines and markers grown in the same condition together.” (See page 24, first full paragraph.) Producing a fingerprint (e.g., a vector) comprising morphological values (alone or in combination with other types of information) requires only routine mathematical or algorithmic skill using the teachings of the present specification. Essentially, all that is required is a computational mechanism for grouping or associating the constituent morphological values (or derivations thereof) with one another. Applicants respectfully point out that the Office appears to have previously realized that such an embodiment of the invention is fully enabled by Applicants’ disclosure in view of what is known in the art; indeed, in Paper No. 21 the Office indicated that Applicants’ specification enables a fingerprint implementation of the disclosed invention. (See Paper No. 21 at page 3.)

In now making the enablement rejection of such a fingerprint implementation, the Office quotes a passage from *Fields v. Conover*, 176 U.S.P.Q. 276 (C.C.P.A. 1970), in which the Court quoted a passage from *I Robinson on Patents* 451 (1890). While the quoted passage includes a statement to the effect that a disclosure must allow the public to practice a claimed invention *without experimentation*, the Court made explicitly

clear that this is not the proper standard by which enablement is judged. *Fields v. Conover*, 176 U.S.P.Q. at 279. Rather, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988); *Fields v. Conover*, 176 U.S.P.Q. at 279.

Applicants submit that one of skill in the art is able to produce a fingerprint based on Applicants' disclosure, without undue experimentation. Thus, Applicants submit that the invention as claimed is fully enabled.

Applicants would also like to respectfully remind the Office that it is the Office which bears the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 2d 1510, 1515 (Fed. Cir. 1993). Applicants submit that the Office has not met its burden by merely stating that decisions, judgments, and tests require more than routine experimentation, while providing no reason as to why this is the case.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Office rejected claims 40-43 and 51 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. (Office Action at page 6.) In particular, the Office stated that the claim recitation "fingerprints associated with known behaviors in a database" is vague and indefinite. Applicants note that amended claim 40 recites "statistically comparing said fingerprint against fingerprints associated with application of said manipulation to cell lines in a database." Applicants submit that this language makes clear that the database contains fingerprints obtained from cell lines following manipulations, and that the database is constructed so that each fingerprint is

associated with information including the cell lines and manipulations from which it was obtained. Applicants submit that this language is clear and definite.

Conclusion

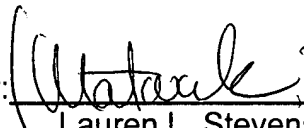
Applicants respectfully maintain that all pending claims are in condition for allowance. Therefore, Applicants respectfully request a Notice of Allowance for this Application from the Examiner. Should any unresolved issues remain, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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